UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All Cases	)	

MEMORANDUM IN SUPPORT OF EMERGENCY MOTION TO COMPEL SUPPLEMENTATION OF PLAINTIFFS' STEERING COMMITTEE'S RULE 26 EXPERT REPORTS

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "STOPNC Defendants"), submit this Memorandum in Support of the Emergency Motion to Compel Supplementation of the Plaintiffs' Steering Committee's ("PSC") Rule 26 Expert Reports.

The PSC's Rule 26 expert reports violate Fed. R. Civ. P. 26(a)(2)(B)(ii). The reports do not disclose the information necessary to identify the material facts and data considered by the experts in forming their opinions. The STOPNC Defendants move this Court, on an emergent basis, to enter an order compelling the PSC to immediately supplement its Rule 26 expert reports to identify all materials considered by its experts with sufficient detail, as required by Fed. R. Civ. P. 26(a)(2)(B)(ii), to permit the STOPNC Defendants to locate and review this information.

I. Background, Meet and Confer Process, and Need for Quick Resolution

On December 16, 2015, the PSC disclosed ten (10) "Common" Expert Witnesses and their corresponding Rule 26 reports.[1] These reports do not meet the requirement of Fed. R. Civ. P. 26(a)(2)(B)(ii) to disclose all "the facts or data considered by the witness in forming" his or her opinion.

On December 30, 2015, the STOPNC Defendants contacted the PSC and requested that the reports be supplemented with sufficient detail to permit the STOPNC Defendants to identify the specific materials the PSC's witnesses reviewed in forming their opinions. The STOPNC Defendants provided the PSC with specific examples of the reports' deficient disclosures, and offered to discuss any concerns the PSC had regarding the requested supplementation. The PSC's response, sent six (6) minutes after it received the STOPNC Defendants' email, consisted of a single paragraph that misrepresented the procedural history of the issue, took a hypocritical position in regards to working over a holiday, and stated it would not consider or respond to the STOPNC Defendants' request for supplementation until "the week of January 5."

The STOPNC Defendants responded to the PSC on December 31, 2015, again requesting supplementation. Despite the tight deadlines governing the immediate work at hand, the PSC waited until January 4, 2016, to respond to the request. In its response, the PSC disagreed that its experts' reports lacked the information necessary to identify the materials upon which its experts relied. Ignoring the charge of the PSC, and adding additional delay, the PSC instructed counsel for the STOPNC Defendants to communicate their supplementation requests in writing with the individual Plaintiff's

[1] Doc. 2516.

attorneys who specifically retained each expert. The PSC concluded by stating "we will do our best to promptly respond to such specific requests."

The STOPNC Defendants responded the same day and specifically identified the portions of each disclosure that needed to be supplemented and requested that supplementation occur by January 6, 2016. On January 6, 2016, the PSC replied that it was coordinating with co-counsel to produce a response "that will include additional descriptions" by Monday, January 11, 2016.[2]

As the Court is aware, the deadlines for common expert discovery are incredibly tight, with the STOPNC Defendant's rebuttal expert reports due January 15, 2016, the PSC's reply expert reports due on January 29, 2016, and common expert discovery closing on February 19, 2016. The impending deadlines and the PSC's continued delay in providing supplemental information, information that should have already been disclosed under Rule 26(a)(2)(B)(ii), illustrates the need for this dispute to be settled as soon as possible.

II. Legal Argument for Supplementation

A. FRCP 26 requires that an expert report contain an adequate description of the materials reviewed and relied upon in forming the opinions.

Fed. R. Civ. P. 26(a) requires disclosure of six (6) categories of information, one of which is the facts or data considered by the expert in forming his or her opinion.[3] An expert must disclose these facts and data, and the disclosure should be "detailed and complete."[4]

[2] See Exhibit 1, email correspondence.
[3] Fed. R. Civ. P. 26(a)(2)(B)(ii).
[4] Fed. R. Civ. P. 26 Advisory Committee Notes.

These requirements "embody the underlying principle that animates modern discovery doctrine: the parties should be allowed to obtain 'the fullest possible knowledge of the issues and facts before trial,'"[5] eliminate unfair surprise, and conserve resources[6]. Without identification of the specific information relied upon by the experts, cross-examination of the witness on the substance of the relied upon information is impossible.[7]

"When the expert is relying on specific records or documents to render certain opinions, [Rule 26] requires that the expert identify those specific records or documents. Without that identification, the opposing party has no way of testing the accuracy and reliability of the opinions."[8] The test to determine if a disclosure has satisfied the Rule 26 requirements is "whether it was sufficiently complete, detailed and in compliance with the Rules so that surprise is eliminated, unnecessary depositions are avoided, and costs are reduced."[9] Disclosures that are "sketchy" or "vague" do not satisfy the Rule 26 requirements.[10]

In some respects, the PSC's reports are compliant. However, in others – listed below – there is just not enough detail in the description of the materials reviewed and relied upon to allow the Defendants to cross-examine the witnesses on the materials.

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[5] *LeBarron v. Haverhill Co-op. School Dist.*, 127 F.R.D. 38, 40 (D. N.H. 1989) citing 8 C. Wright & A. Miller, *Federal Practice and Procedure: Civil* § 2001, at 13.
[6] *See Sylla – Sawdon v. UniRoyal Goodrich Tire Co.*, 47 F.3d 277, 284 (8th Cir. 1995).
[7] *Cohlmia v. Ardent Health Services, Inc.*, 254 F.R.D. 426, 433 (N.D. Okla. 2008) ("Defendants cannot depose these witnesses on the basis of the existing reports because they do not set forth the reasons or methodology supporting their opinions").
[8] *Adams v. U.S.*, 2011 WL 3841012 at 1 (D. Idaho 2011).
[9] *Reed v. Binder*, 165 F.R.D. 424, 429 (D. N.J. 1996).
[10] Fed. R. Civ. P. 26 Advisory Committee Notes.

B. Illustrative cases demonstrate that experts must describe the materials reviewed and relied upon with sufficient particularity to allow the opposing party to evaluate the bases of the opinions.

Four court opinions illustrate the analysis this Court should take:

i. *Cohlmia v. Ardent Health Services*

The decision in *Cohlmia v. Ardent Health Services, LLC*[11] makes clear the specificity required by Rule 26. *Cohlmia* involved claims of antitrust, defamation, and tortious interference with economic advantage following a physician's suspension from the medical staff of a hospital. The defendants asserted that the plaintiff's experts' reports failed to satisfy the Rule 26 requirements due to, in part, a lack of specificity in the facts and data considered by the experts in forming their opinions.

The plaintiff's antitrust expert's report stated that his opinions were based on pleadings, discovery material, "additional publicly available materials also referenced throughout this report," and "'data' that he is 'accumulating and reviewing.'"[12] However, the report failed to specify any of the "additional publicly available materials" or disclose the data he was "accumulating and reviewing."[13]

The plaintiff's peer review expert's report noted that his opinions were based on his knowledge and experience as a medical doctor, his knowledge of the internal procedures of the peer review process, his review of "certain documents including transcripts from the [plaintiff's] peer review/disciplinary proceedings, certain pleadings, and certain discovery pleadings," the record of the plaintiff's suspension, and the testimony of another physician.[14] However, the report failed to "cite to anything specific

[11] *Cohlmia*, 254 F.R.D. at 426.
[12] *Cohlmia*, 254 F.R.D. at 431.
[13] *Id. at* 431.
[14] *Id.*

in the record or transcript" from the plaintiff's suspension and offered "no details as to what in the [other physician's] testimony he relies upon or how that testimony factored into any of his preliminary conclusions."[15]

In finding that neither report satisfied the Rule 26 disclosure requirements, the court noted that the reports "wholly fail to disclose, in any intelligible way, the facts and rationale which underlie the opinions expressed. As such, the reports provide virtually no assistance to opposing counsel in preparing to cross-examine [the experts]."[16]

ii. *Kerlinsky v. Sandoz*

Kerlinsky v. Sandoz, Inc. involved a suit against a drug manufacturer for injuries the plaintiff allegedly sustained after taking Terazosin, a prescription medication. The plaintiff disclosed an expert witness whose report stated that her opinions were based on "studies including readings pertaining to Terazosin."[17]

The defendants filed a motion to strike the expert on the grounds that her report failed to comply with the requirements of Rule 26, citing, among other things, that the report "does not disclose the facts or data she considered in arriving at her conclusions." The court agreed with the defendants and granted the motion to strike noting that the report failed to provide "any specific references whatsoever" to the "readings pertaining to Terazosin."[18]

[15] *Id.*
[16] *Id.* at 432.
[17] *Id.* at 240.
[18] *Id.* at 241.

iii. *Olmstead, Inc. v. CU Interface, LLC*

R.C. Olmstead, Inc. v. CU Interface, LLC[19] arose from allegations of theft of proprietary software. The plaintiff's expert's report noted that he based his opinion on a comparison of the plaintiff's software and the allegedly stolen software, and included an attachment consisting of 197 pages of screenshots that contained no table of contents, and little semblance of order.[20]

The defendants sought to bar the use of the expert's report due to, among other things, a failure to comport with the Rule 26(a)(2)(B(ii) requirements. The court agreed with the defendants and held that the report was "lacking in [the] respect" of the Rule 26(a)(2)(B)(ii) requirement to disclose the data and facts considered by the witness in forming his opinion.[21] The court specifically noted that, although three (3) different versions of the plaintiff's software had been produced in discovery, the expert's report failed to state which version was compared to the allegedly stolen software. Given that this was among "the most important data considered by [the expert] in forming his opinion…his failure to include in his report which version of the software was considered is flatly unacceptable…"[22] The court further noted that the report made no reference to the screenshots he considered and the "lack of keying or reference between the opinions and the reviewed materials violated Rule 26(a)(2)(B)'s command to be 'detailed and complete.'"[23]

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[19] *R.C. Olmstead, Inc. v. CU Interface, LLC*, 657 F.Supp.2d 905 (N.D. Ohio 2008).
[20] *Id.* at 907.
[21] *Id.* at 910.
[22] *Id.*
[23] *Id. at* 910-11.

iv. *D.G. ex rel. G. v. Henry*

D.G. ex rel. G. v. Henry[24] provides a final example that the disclosure of the facts and data considered in forming an opinion must be detailed and specific. The expert's report in *Henry* generally referred to statutes and policies considered in forming his opinion. The defendants sought an order compelling the plaintiffs to provide all of the facts and data considered by the expert in forming his opinion, including the specific statutes and policies he considered.[25] Relying upon the language of Rule 26(a)(2)(B)(ii), the court ordered the plaintiffs to disclose the "specific statutes and policies, including identification of the year or version if they are publicly available…" that the expert considered.[26]

* * * * * * * *

Rule 26 requires disclosures of the facts and data considered by an expert in forming his or her own opinion. The disclosures must be detailed and complete as to allow the opposing party an opportunity to test the accuracy and reliability of the opinions, avoid surprise, limit depositions, and reduce costs.

III. Deficiencies in the PSC's Expert's Reports

Almost all of the PSC's expert reports are deficient because the reports fail to describe with sufficient particularity the materials relied upon by the expert. Without identification of the materials relied upon, the Defendants cannot review those materials and prepare to cross-examine the witness.

[24] *D.G. ex rel. G. v. Henry*, 2011 WL 1344200 (N.D. Okla. 2011).
[25] *Id.* at 1.
[26] *Id.* at 2.

The following table identifies the specific disclosures in need of supplementation.

Relevant Expert Report(s)	Description in Report of Information Reviewed and Relied Upon	Problem with Description	Supplementation Sought
John Braddley, M.D.[27] Erik Dubberke, M.D.[28] Richard Rauck, M.D.[29] John Stevenson, M.D.[30] Larry Winikur, M.D.[31]	Reviewed medical records of patients receiving epidural steroid injections.	This does not allow the Defendants to identify *which* of the hundreds of patients' records were reviewed to form the opinions. Without this, the Defendants cannot review the records to test the opinions.	The names of the patients and the records reviewed.
John Braddley, M.D.[32]	Reviewed "information regarding products recalled by NECC"	This description is so vague that it could encompass millions of pages of documents from this litigation.	The specific information reviewed.
Vickie Dawson, R.N.[33] James Gray, Pharm.D[34] Richard Rauck, M.D.[35] John Stevenson, M.D.[36] Larry Winikur, M.D.[37]	Reviewed "documents regarding the regulatory history of NECC"	Thousands of pages of relevant documents fit this category. Without specification, the Defendants cannot prepare to cross-examine these witnesses on important points from the documents.	The specific documents reviewed.
Vickie Dawson, R.N.[38] James Gray, Pharm.D.[39] Richard Rauck, M.D.[40] John Stevenson, M.D.[41] Larry Winikur, M.D.[42]	Reviewed "certain Federal, Tennessee, and Massachusetts pharmacy laws governing pharmacy compounding"	Without identification of the laws, the Defendants cannot cross-examine the witnesses about the laws.	The specific laws reviewed.

[27] Exhibit 2, Report of Opinions of John W. Baddley, M.D., at pg. 1.
[28] Exhibit 3, Report of Opinions of Erik Dubberke, M.D., at pg. 1.
[29] Exhibit 4, Report of Opinions of Richard L. Rauck, M.D., at pg. 2.
[30] Exhibit 5, Report of Opinions of John H. Stephenson, M.D., at pg. 3.
[31] Exhibit 6, Report of Opinions of Lawrence J. Winikur, M.D., at pg. 2.
[32] Exhibit 2 at pg. 2.
[33] Exhibit 7, Report of Opinions of Vickie Dawson, M.S.N., R.N., C.N.O.R., at pg. 2.
[34] Exhibit 8, Report of Opinions of James L. Gray, III, Pharm.D., M.B.A., at pg. 1.
[35] Exhibit 4 at pg. 2.
[36] Exhibit 5 at pg. 2.
[37] Exhibit 6 at pg.2.
[38] Exhibit 7 at pg. 3.
[39] Exhibit 8 at pg. 2.
[40] Exhibit 4 at pg. 2.
[41] Exhibit 5 at pg. 3.
[42] Exhibit 6 at pg. 2.

Vickie Dawson, R.N.[43] James Gray, Pharm.D.[44] Richard Rauck, M.D.[45] John Stevenson, M.D.[46] Larry Winikur, M.D.[47]	Reviewed "information published by the FDA regarding compounding drug products"	Thousands of pages of relevant documents fit this category. Without specification, the Defendants cannot prepare to cross-examine these witnesses on important points from the documents.	The specific information reviewed.
Vickie Dawson, R.N.[48] James Gray, Pharm.D.[49] Richard Rauck, M.D.[50] John Stevenson, M.D.[51] Larry Winikur, M.D.[52]	Reviewed "information from the CDC, including the MMWR dated 12/13/12"	This description leaves open the question of whether additional CDC documents will be relied upon by the witness.	Any additional CDC information reviewed.
John Braddley, M.D.[53] Erik Dubberke, M.D.[54]	Reviewed "information from the CDC, including MMWR dated 10/19/12"	This description leaves open the question of whether additional CDC documents will be relied upon by the witness.	Any additional CDC information reviewed.
Vickie Dawson, R.N.[55] James Gray, Pharm.D.[56] Richard Rauck, M.D.[57] John Stevenson, M.D.[58] Larry Winikur, M.D.[59]	Reviewed "information published by the ASHP warning the pharmacy and medical communities of the risks of using compounding drugs"	Without identification of the documents, the Defendants will not be able to prepare to cross-examine the witnesses on the contents of the documents.	The specific information reviewed.

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The PSC unquestionably failed to satisfy the requirement of Rule 26(a)(2)(B)(ii). The claims to the contrary by the PSC demonstrate a lack of good faith participation in the meet and confer process. The disclosures do not possess the detail to permit the STOPNC Defendants to identify and catalogue the alleged evidence supporting the

[43] Exhibit 7 at pg. 3.
[44] Exhibit 8 at pg. 2.
[45] Exhibit 4 at pg. 2.
[46] Exhibit 5 at pg. 3.
[47] Exhibit 6 at pg. 2.
[48] Exhibit 7 at pg. 2.
[49] Exhibit 8 at pg. 1.
[50] Exhibit 4 at pg. 2.
[51] Exhibit 5 at pg. 3.
[52] Exhibit 6 at pg. 2.
[53] Exhibit 2 at pg. 1.
[54] Exhibit 3 at pg. 1.
[55] Exhibit 7 at pg. 3.
[56] Exhibit 8 at pg. 2.
[57] Exhibit 4 at pg. 2.
[58] Exhibit 5 at pg. 3
[59] Exhibit 6 at pg. 2.

opinions, and then to test the accuracy, reliability, and "fit" of the facts and data considered by the PSC's witnesses in forming their opinions.

The cases cited above all embrace the principle that an expert report must disclose the facts and data reviewed with specificity. A general disclosure of "information published by the FDA," "information published by the ASHP," "documents regarding the regulatory history of NECC,"[60] or "certain Federal, Tennessee, and Massachusetts pharmacy laws"[61] does not satisfy Rule 26.

IV. Conclusion

The PSC's expert reports do not satisfy the Rule 26(a)(2)(B)(ii) requirement to adequately disclose the facts and data the witnesses considered in reaching their opinions. The reports fail to disclose this information in a detailed and complete fashion so as to eliminate surprise, limit depositions, reduce costs, and allow the STOPNC Defendants to test the accuracy and reliability of the PSC's witnesses' opinions.

Therefore, having established that the PSC's expert reports fail to satisfy the requirements of Rule 26(a)(2)(B)(ii), and in light of the PSC's continued delay to supplement this information in light of the impending discovery deadlines, the STOPNC Defendants respectfully request the Court, on an emergent basis, issue an order

[60] The Massachusetts Board of Regulation in Pharmacy and the FDA produced and made publicly available nearly 40,000 pages of "documents regarding the regulatory history of NECC." Surely, the PSC's witnesses did not review all 40,000 pages. Any argument by the PSC that a disclosure of "information regarding the regulatory history of NECC" is sufficiently detailed and complete as to allow the STOPNC Defendants to identify the specific documents reviewed and therefore eliminate surprise, limit depositions, and reduce costs, is ludicrous, but hardly humorous given the limited time to complete common discovery.

[61] *D.G. ex rel. G. v. Henry* establishes that a disclosure stating "statutes" were generally considered in forming an opinion does not satisfy the Rule 26 requirements. Directly on point, *Henry* validates the pending motion regarding the PSC's vague disclosures regarding unspecified Federal, Tennessee, and Massachusetts laws supposedly considered by one or more "experts."

compelling the PSC to immediately supplement its expert reports consistent with the chart above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 6th day of January, 2016.

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